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10/644,601

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EXAMINER

SONNETT, KATHLEEN C

ART UNIT

PAPER NUMBER

3731

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/644,601 | Applicant(s) MASKET, SAMUEL | |
| | Examiner KATHLEEN SONNETT | Art Unit 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Double Patenting***

1. Applicant is advised that should claim 38 be found allowable, claim 52 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. It appears to the examiner that any transferable marking material can be considered a dye or stain. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. **Claims 38-52** are rejected under 35 U.S.C. 103(a) as being unpatentable over Cozean, Jr. et al. (US 5,873,883; "Cozean") in view of Lash (US 5,728,117). Cozean discloses a tool for use during a capsulotomy procedure comprising an assembly capable of marking a lens capsule (for example, by leaving a physical impression) containing a resiliently flexible metallic marking element having a substantially ring-shaped distal portion in a natural state, wherein the marking assembly is able to be deformed (fig. 4; col. 3 ll. 13-17). The ring-shaped distal portion is substantially contained in a plane when in the deployed condition and has an upper blunt edge and opposing lower blunt edge (see fig. 3; edges 22, 26). The edges are blunt as seen in fig. 3 and the cutting is carried out by a high pressure fluid cutting medium. The marking element can engage the lens capsule during non-damaging contact when the fluid is not being

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expelled. Cozean fails to disclose a transferable marking material applicable to at least one of the upper and lower blunt edge of the substantially ring-shaped distal portion of the marking element and also fails to disclose a shaft into which the marking assembly is housed in a transport condition.

4. Lash teaches that it is well known to provide a dye on the edge of a cutting instrument that is pressed against the lens capsule so that the location of the incision is marked (col. 4, ll. 49-54; "35", fig. 6). It would have been obvious to one skilled in the art to have modified Cozean to include such a transferable marking material on at least the blunt edge near channel (26) where the cutting is eventually effectuated by fluid flow so that the location of the incision may be marked by the surgeon as taught by Lash. Lash further teaches including a deformable cutting instrument within an elongated shaft so that the instrument can be inserted through a small incision in order to minimize tissue damage (figs. 1-5). One skilled in the art would also recognize that housing the marking assembly within the shaft during insertion and withdrawal helps avoid unnecessary marks caused by accidental contact between the marking assembly and surrounding tissue. Therefore, it would have been obvious to one skilled in the art to have modified the device of Cozean in view of Lash to include a shaft in which the marking assembly may be housed in a transport condition so that it too would have these advantages.

5. Regarding claim 39, the ring-shaped portion has an associated size which is adjustable by the user. That is to say, when the user actuates the tool such that the ring-shaped portion is within the elongated shaft, the ring-shaped portion is one size and when it is freed from the shaft, it has another size as taught by Lash (see figs. 2 and 3 of Lash).

6. Regarding claims 40 and 41, the transferable marking material on the ring-shaped distal portion of the marking element taught by Lash is a dye.

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7. Regarding claims 42, 43, 45, and 46, the transfer of the marking material leaves a circular ring-shaped mark on the lens formed by the marking material since the metallic marking element is ring-shaped (figs 1-3 of Cozean). It is noted that a circle is an ellipse (with an eccentricity of 0) and therefore can be considered an elliptical shape.

8. Regarding claim 44, the ring-shaped portion is operable to be configured into a first and second shape and size (figs. 2, 3 of Lash).

9. Regarding claims 47 and 49, the ring-shaped portion is metal (stainless steel; col. 3 ll. 1-4 of Cozean) and can be considered shape-memory as it returns to an expanded shape after it has been deformed (col. 3, ll. 13-17 of Cozean).

10. Regarding claim 48, the size and dimension of the elongated shaft taught by Lash is suitable for insertion of the delivery mechanism through a cataract incision (34) made in a cornea of the eye.

11. Regarding claim 51, Lash teaches a plunger-type marking element retraction/extension mechanism which allows the user to easily control deployment of the marking assembly and therefore it would have been obvious to one skilled in the art to add such a feature to the device of Cozean (see 14, 16, 18 of Lash).

12. Regarding claim 52, the tool comprises a dye on the ring-shaped portion of the marking element.

13. Regarding claim 50, Cozean in view of Lash discloses the invention substantially as stated above but fails to disclose the retraction/extension mechanism as being screw-type. However, it is old and well known in the art to make a retraction/extension mechanism of a medical instrument a screw-type mechanism (as admitted by applicant on p. 10, ll. 8-11 of applicant's specification) in order to obtain the well known advantage of very precisely controlling the retraction or extension of the instrument. It would have been obvious to make

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retraction/extension mechanism of Cozean in view of Lash a screw-type mechanism so that it too would have this advantage.

14. **Claim 53** is rejected under 35 U.S.C. 103(a) as being unpatentable over Cozean in view of Lash as applied to claim 53 above and further in view of Nallakrishnan (US 5,752,960).

Cozean in view of Lash discloses the invention substantially as stated above except for the marking element being contained in a plane that intersects a longitudinal axis of the elongated shaft.

15. However, Nallakrishnan teaches that it is old and well known in the art to bend the distal portion of an instrument used for ocular surgery relative to the longitudinal axis of the rest of the instrument. Such a bend is advantageous because it facilitates insertion of the distal portion of the device into a patient's eye (fig. 3; col. 5 ll. 11-17). It would have been obvious to one skilled in the art to modify the device of Cozean to include that the marking element, when deployed, is at an oblique angle to the longitudinal axis of the elongated shaft as made obvious by Nallakrishnan in order to facilitate insertion of the marking element into a patient's eye.

Response to Arguments

16. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHLEEN SONNETT whose telephone number is (571)272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 11/17/2008

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731